

## DETAILED ACTION

### ***Election/Restrictions***

Claims 1, 3-6, 8, 10-11, 21-22, 24-27 are allowable. The restriction requirement Species, as set forth in the Office action mailed on 06/17/08, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 12-20, 23, either directed to a medical device with different species are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim. However, claims 28-32, directed to pump apparatus and method of infusing a medication in to a patient withdrawn from consideration because they do not require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Marc A. Began on 11/04/10.

The application has been amended as follows:

AMENDMENTS TO THE CLAIMS:

LISTING OF CLAIMS

1. (Currently Amended) A medical device, comprising:

- a lower mounting surface adapted for application towards the skin of a subject,
- a sheet member extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin,
- a transcutaneous device adapted to penetrate the skin of the subject and being mounted for movement between an extended position in which the transcutaneous device projects relative to the lower mounting surface and a retracted position in which the transcutaneous device is retracted relative to the lower mounting surface,
- a release attached directly to a peripheral portion of the sheet member, the release comprising a user gripable portion moveable relative to the lower mounting surface, the user gripable portion being operatable from a first condition through an intermediate condition to a second condition,
- whereby operation of the user gripable portion from the first to the intermediate condition causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the user gripable portion from the intermediate to the second condition causes release of the sheet member from the skin.

2. (Cancelled)

3. (Currently Amended) A medical device as in claim 2 1, wherein the release comprises:

transcutaneous device retraction means operatable between a first state in which the transcutaneous device projects relative to the lower surface and a second state in which the transcutaneous device is retracted relative to the lower surface, the transcutaneous device retraction means being moved between its first and second states when the user gripable portion is operated from the first to the intermediate state.

4. (Previously Presented) A medical device as in claim 3, wherein:

- the transcutaneous device retraction means is operatable connected to the user gripable portion such that the transcutaneous device retraction means is moved between its first and second

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states when the user gripable portion is operated from the first to the intermediate state, and wherein

- the medical device is pulled off the skin of the subject when the user gripable portion is operated from its intermediate state to its second state.

5. (Previously Presented) A medical device as in claim 3, wherein the user gripable portion and the transcutaneous device retraction means are operatable connected to each other allowing movement of the user gripable portion to be transferred to the transcutaneous device retraction means.

6. (Previously Presented) A medical device as defined in claim 3, wherein the transcutaneous device retraction means comprises a flexible strip portion arranged below a portion of the transcutaneous device, whereby the flexible strip portion will lift the transcutaneous device from the extended position to the retracted position when the user gripable portion is operated from the first to the intermediate state.

7. (Cancelled)

9. (Cancelled)

10. (Previously Presented) A medical device as in claim 1, wherein the transcutaneous device is a fluid delivery device comprising a distal end adapted to penetrate the skin of the subject and a proximal end adapted to be arranged in fluid communication with a fluid supply.

11. (Previously Presented) A medical device as in claim 1, further comprising coupling means for releasable securing the transcutaneous device unit to a mating structure, wherein the transcutaneous device is a fluid delivery device comprising a distal end adapted to penetrate the skin of the subject and a proximal end adapted to be arranged in fluid communication with a fluid supply.

12. (Rejoined) A medical device as in claim 1, wherein the transcutaneous device is a fluid delivery device, the medical device further comprising:

- a housing,
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the fluid delivery device to be arranged in fluid communication with an interior of the reservoir, and
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the fluid delivery device.

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13. (Rejoined) A medical device as in claim 1, in combination with a pump unit comprising: - a mounting surface adapted for application against the skin of a subject,

- a reservoir adapted to contain a liquid drug,
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the transcutaneous device,
- wherein the attaching means is adapted for securing the medical device to the pump unit and thereby relative to the skin of the subject, and
- whereby operation of the release means from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second state causes release of medical device from the pump unit.

14. (Rejoined) A combination as in claim 13, wherein a receiving portion of the pump unit and a corresponding portion of the medical device comprise the attaching means in the form of mating, releasable coupling means allowing the medical unit to be secured to the pump unit.

15. (Rejoined) A combination as in claim 13, wherein the mounting surface comprises an aperture, the transcutaneous device unit being secured relative to the mounting surface with the transcutaneous device in register with the aperture, the transcutaneous device being adapted to extend through the aperture in its extended position.

16. (Rejoined) A medical device as in claim 1, in combination with a pump unit comprising: - a reservoir adapted to contain a liquid drug,

- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the transcutaneous device,
- wherein the medical device and the pump unit comprise mating coupling means allowing the pump unit to be releasable attached to the medical device.

17. (Rejoined) A combination as in claim 13, wherein the transcutaneous device is moved from its initial to its extended position when the medical device and the pump unit are attached to each other.

18. (Rejoined) A medical device as in claim 1, in combination with a pump unit and a base plate unit, the

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base plate unit comprising:

- an upper surface and a lower mounting surface adapted for application against the skin of a subject, the mounting surface comprising mounting means having an adhesive surface, the pump unit comprising:
- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the transcutaneous device to be arranged in fluid communication with an interior of the reservoir,
- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the transcutaneous device,
- the pump unit and the base plate unit comprising mating, releasable coupling means allowing the pump unit to be secured to the base plate unit,
- wherein the attaching means is adapted for securing the medical device to the pump unit and/or the base plate unit and thereby relative to the skin of the subject, and
- whereby operation of the release means from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release means from the intermediate to the second state causes release of medical device from the pump unit.

19. (Rejoined) A medical device as in claim 1, further comprising a first peelable sheet having an upper surface and an adhesive lower surface, the upper surface being adapted for peelable detachment from a lower mounting surface.

20. (Rejoined) A medical device or combination as in claim 19, comprising at least one further peelable sheet, each further peelable sheet comprising an upper surface and an adhesive lower surface, the first and the further peelable sheets being arranged in a stacked arrangement with their respective upper surfaces attached to the overlying adhesive surface.

21. (Currently Amended) A medical device comprising:

- a mounting surface adapted for application to a skin site,
- a sheet member extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin

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- an adhesive for securing the mounting surface to the skin site, - a transcutaneous device adapted to penetrate the skin at the skin site, the transcutaneous device being mounted for movement between an initial position in which the transcutaneous device is retracted relative to the lower surface and an extended position in which the transcutaneous device projects relative to the lower surface, and for movement between the extended position and a retracted position in which the transcutaneous device is retracted relative to the lower surface,

- actuation means comprising a first user gripable portion moveable relative to the mounting surface, the first user gripable portion being moveable to cause the transcutaneous device to be moved from the initial position to the extended position, and a release attached directly to a peripheral portion of the medical device and comprising a second user gripable portion moveable relative to the housing, the second user gripable portion being moveable to cause the transcutaneous device to be moved from the extended position to the retracted position, the release further allowing a pulling force to be applied to the peripheral portion of the medical device to thereby remove the medical device when secured to the skin site, wherein the release is attached to a peripheral portion of the sheet member.

- wherein in an initial state the first user gripable portion at least partially covers the second user gripable portion, such that the second user gripable portion is exposed when the first user gripable portion is moved to cause the transcutaneous device to be moved from the initial position to the extended position.

22. (Currently Amended) A medical device comprising:

- a mounting surface adapted for application towards a skin site, a sheet member extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin

- a transcutaneous device adapted to penetrate the skin at the skin site, the transcutaneous device being mounted for movement between an initial position in which the transcutaneous device is retracted relative to the lower surface and an extended position in which the transcutaneous device projects relative to the lower surface, and for movement between the extended position and a retracted position in which the transcutaneous device is retracted relative to the lower surface,

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- actuation means comprising a first user actuatable portion being actuatable to cause the transcutaneous device to be moved from the initial position to the extended position, and release means comprising a second user actuatable portion actuatable to cause the transcutaneous device to be moved from the extended position to the retracted position,

- wherein the release means cannot be actuated before the actuation means has been actuated and wherein the release means is attached directly to a peripheral portion of the sheet member.

23. (Rejoined) A medical device as in claim 21, wherein the transcutaneous device is a fluid delivery device, the medical device further comprising:

- a reservoir adapted to contain a liquid drug and comprising an outlet means allowing the fluid delivery device to be arranged in fluid communication with an interior of the reservoir, and

- expelling means for, in a situation of use, expelling a drug out of the reservoir and through the skin of the subject via the fluid delivery device.

24. (Previously Presented) A medical device as in claim i defined in any of the previous claims, wherein the portion of the transcutaneous device adapted to penetrate the skin of the subject is in the form of a hollow metallic needle comprising an outer smooth coating of a polymeric material.

25.( Previously Amended) A medical device comprising:

a mounting surface for mounting the device towards the skin of a user;

a sheet member extending peripherally relative to the mounting surface and having a lower adhesive surface for securing the mounting surface relative to the skin

a transcutaneous device for penetrating the skin of the user, the transcutaneous device being moveable between an extended position and a retracted position;

a release comprising a user graspable portion, the user graspable portion being moveable to cause the transcutaneous device to be moved from the extended position to the retracted position, the release further being coupled to the medical device in a manner that allows the user to exert a force on the medical device to remove the medical device away from the user's skin after the transcutaneous device has been moved from the extended position to the retracted position, wherein the release is attached directly to a peripheral portion of the sheet member.

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26. (Original) The device of claim 25, further comprising an adhesive on the mounting surface.

27. (Currently Amended) An apparatus comprising:

- a surface,

a sheet member extending peripherally relative to the surface and having a lower adhesive surface for securing the surface relative to the skin

- a transcutaneous device adapted to penetrate the skin of a subject,

- the transcutaneous device being moveable between an extended position in which the needle projects relative to the surface and a retracted position in which the needle is retracted relative to the surface,

- a coupling for releasably securing the transcutaneous device unit to a mating structure,

- a release operatable from a first state through an intermediate state to a second state,

- wherein operation of the release from the first to the intermediate state causes the transcutaneous device to be moved from the extended position to the retracted position, and operation of the release from the intermediate to the second state causes release of the coupling and wherein the release is attached directly to a peripheral portion of the sheet member.

28-32. (Cancelled).

#### ***Allowable Subject Matter***

Claims 1, 3-6, 8, 10-27 are allowed.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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